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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,514	11/01/2004	Hoon Choi	1599-0269PUS1	8899

2292 7590 08/28/2006

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EXAMINER

BALLS, ROBERT J

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/510,514	Applicant(s) CHOI ET AL.	
	Examiner R. James Balls	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-13 are pending.
2. This application is a 371 of PCT/KR03/00683 filed on April 4, 2003, which claims foreign priority to REPUBLIC OF KOREA 10-2002-0018847 filed on April 8, 2002.
3. Claims 1-11 and new Claims 12-13 are currently under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The rejection of Claims 1-11 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,869,670 in view of Khomutov et al., *Novel Acid-Free Cleavage of N-(2-hydroxyaryliene) protected amines*, TETRAHEDRON LETT., 42:2887-2889 (2001) is maintained for the reasons of record (and is also applicable to newly added claims 12-13). Applicants arguments are: (1) that the instant invention uses a one-pot method by eliminating a recrystallization step; and (2) the instant method provides improved yields over the prior art.

First, applicants' argue that eliminating a recrystallization step from the prior art results in one-pot process for the production of Gemifloxacin. However, neither the claims nor the examples of the prior art require (or even mention) a recrystallization

step. Example 180 in column 94 describes the process for producing Gemifloxacin. The specification explains that Gemifloxacin precipitates out as a solid at 85% yield, but does not mention a recrystallization step. Also, Claims 1-2 of the prior art sets forth the preparation of Gemifloxacin. Again, there is no mention of a recrystallization step. Furthermore, even if the prior art required a recrystallization step, Khomutov et al. specifically teaches that using a Schiff-base type protecting group is desirable because it reacts exclusively with an NH_2 group in the presence of a secondary amine, in a one-pot procedure. See p. 888, first column, first full paragraph. Therefore, one of ordinary skill in the art would be motivated to employ the protecting groups taught by Khomutov et al. to make Gemifloxacin in a one-pot procedure, with recrystallization being a separate, optimizing addition to the over all synthesis.

Second, applicants point out that the instant process of preparing acid salts of Gemifloxacin provides higher yields of product than the prior art process. To overcome a rejection of obviousness, the property of a result must actually be unexpected. *In re Skoll*, 187 USPQ 481; *In re Coleman*, 205 USPQ 245. As mentioned above, Khomutov et al. suggested that using a Schiff-base type protecting group is desirable because it reacts exclusively with an NH_2 group in the presence of a secondary amine. See p. 888, first column, first full paragraph. Therefore, one of ordinary skill in the art would be motivated to employ such suggestion and expect exclusivity. Also, modification of a known process through suggestion of the prior art is within the expectation that yields may vary with modification. When comparing chemical processes to show unexpected results, data must be accompanied with statistical analysis showing experimental error,

reproducibility, and significant figures in order to be persuasive. Mere arguments absent competent factual support are entitled to little probative value. *In re Lindner* 173 USPQ 356.

Double Patenting

5. The obvious-type double patenting rejection of Claims 1-11 over U.S. Patent No. 5,869,670 in view of Khomutov et al. is maintained for the reasons of record (and is also applicable to newly added claims 12-13). Applicants' arguments are: (1) that the instant invention uses a one-pot method by eliminating a recrystallization step; and (2) the instant method provides improved yields over the prior art.

First, applicants' argue that eliminating a recrystallization step from the prior art results in one-pot process for the production of Gemifloxacin. However, neither the claims nor the examples of the prior art require (or even mention) a recrystallization step. Example 180 in column 94 describes the process for producing Gemifloxacin. The specification explains that Gemifloxacin precipitates out as a solid at 85% yield, but does not mention a recrystallization step. Also, Claims 1-2 of the prior art sets forth the preparation of Gemifloxacin. Again, there is no mention of a recrystallization step. Furthermore, even if the prior art required a recrystallization step, Khomutov et al. specifically teaches that using a Schiff-base type protecting group is desirable because it reacts exclusively with an NH₂ group in the presence of a secondary amine, in a one-pot procedure. See p. 888, first column, first full paragraph. Therefore, one of ordinary skill in the art would be motivated to employ the protecting groups taught by Khomutov

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et al. to make Gemifloxacin in a one-pot procedure, with recrystallization being a separate, optimizing addition to the over all synthesis.

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Conclusion

6. No Claims are allowed.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

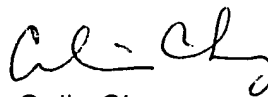
Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls
August 11, 2006



Celia Chang
Primary Examiner
Art Unit 1625